Summary of Safety and Effectiveness K033547

JAN - 7 2004

A. Determination of Substantial Equivalence

VNUS Vessel and Tissue Coagulation System (proprietary name: TBD)

B. Common Name

Bipolar Electrosurgical Instrument

C. Predicate Device(s)

VNUS® Closure® System (K972541);
VNUS® Closure® System (K982816, K003092, and K030557);
Cameron-Miller Vein Eraser System (Pre-amendment); and
ArthroCare Electrosurgery System (K992581)

D. Device Description

The VNUS Vessel and Tissue Coagulation System is a bipolar, high frequency electrosurgical system designed for use in general surgical procedures where blood vessel and tissue coagulation is desired. It consist of three main components: The VNUS Vessel and Tissue Coagulation Device (proprietary name: TBD), the Radiofrequency (RF) Generator, and the Instrument Cable.

The VNUS Vessel and Tissue Coagulation Device is sterile disposable device intended for a single-use only. The device's function is to deliver bipolar RF energy to the desired treatment site and relay temperature and other feedback to the RF Generator. The disposable device is available in three bipolar configurations for selection by the physician based on preference for method of vessel access.

The RF Generator is a high frequency electronic, bipolar, microprocessor / software controlled instrument. It allows the user to set Power, Temperature and Time values, and provides user displays of Power, Temperature and Time (set-points and measured values) as well as measured Impedance and user messages. The RF Generator remains out of the sterile field during use, and is provided non-sterile.

The instrument cable connects the disposable device to the RF generator. The Instrument Cable is provided non-sterile, and is user sterilizable by autoclave. It has been validated to multiple steam sterilization cycles. Both ends of the cable are identical to eliminate connection errors.

E. Intended Use

The VNUS Vessel and Tissue Coagulation System (proprietary name: TBD) is intended for use in vessel and tissue coagulation.

F. Intended Use of Predicate Devices

The specified predicate devices are indicated for "coagulation of blood vessels in patients with superficial vein reflux" (VNUS Closure System), "ablation and coagulation of blood vessels during general surgical procedures" (Cameron Miller Vein Eraser), and "for resection, ablation and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures" (ArthroCare Electrosurgical system).

G. Technological Comparison

The RF energy is widely used in electrosurgical equipment for many years. The safety and efficacy of such devices has been well established for a variety of intended uses. The use of bipolar RF energy delivery has potential advantages over monopolar systems. No grounding pads are required, and the potential for damage to adjacent tissue is minimized, as the patient is no longer the return path for electrical current. The efficiency of bipolar RF energy delivery allows systems such as the VNUS RF Generator to be used at lower voltage and power settings as compared with monopolar systems.

The technological characteristics and principals of operation of the VNUS Vessel and Tissue Coagulation Device (proprietary name: TBD) are substantially equivalent to the noted predicate devices. All devices rely on the delivery of RF energy to achieve their intended use.

H. Discussion of Clinical/Non-Clinical Tests and Conclusions

Performance
Results of in-vitro testing demonstrate that the VNUS Vessel and Tissue Coagulation System (proprietary name: TBD) is safe and effective for its intended function.

Biocompatibility
The materials used in the VNUS Vessel and Tissue Coagulation System (proprietary name: TBD) has been shown to be biocompatible.

I. Summary of Safety and Effectiveness

Based upon the intended use, design, materials, function, comparison with currently marketed devices and the non-clinical testing performed by VNUS, it is concluded that the VNUS Vessel and Tissue Coagulation System (proprietary name: TBD) is substantially equivalent to the noted predicate devices.

Sam Nanavati
Directory, Quality and Regulatory Affairs
VNUS Medical Technologies, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2004

Mr. Sam Nanavati
Director, Clinical Affairs
VNUS Medical Technologies, Inc.
2200 Zanker Road, Suite F
San Jose, California 95131

Re: K033547
Trade/Device Name: VNUS® Vessel and Tissue Coagulation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 10, 2003
Received: November 12, 2003

Dear Mr. Nanavati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name:
VNUS® Vessel and Tissue Coagulation System (proprietary name: TBD)

510(k) Number (if known):
K033547

Indications for Use:

The VNUS Vessel and Tissue Coagulation System (proprietary name: TBD) is intended for use in vessel and tissue coagulation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
(Per 21 CFR 801.109)

or

Prescription Use: ✓

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033547